GENERAL ASSEMBLY
COMMONWEALTH OF KENTUCKY

2016 REGULAR SESSION

SENATE BILL NO. 134

AS ENACTED

TUESDAY, MARCH 29, 2016

AN ACT relating to biological products.

Be it enacted by the General Assembly of the Commonwealth of Kentucky:

➔Section 1. KRS 217.814 is amended to read as follows:

The following words and phrases, as used in KRS 217.815 to 217.826, shall have the following meanings, unless the context requires otherwise:

(1) ***"Biological product" has the same meaning as in 42 U.S.C. sec. 262;***

(2) "Board" means the Kentucky Board of Pharmacy;

(3) "Brand name" means the name that a manufacturer of a drug or pharmaceutical places on the container thereof at the time of packaging;~~[.]~~

(4) "Dosage formulation" shall include but not be limited to those specific dosage forms which, by the nature of their physical manufacture, are deemed to be nonequivalent to other similar formulations such as controlled release tablets, aerosol-nebulizer drug delivery systems, and enteric coated oral dosage forms;

(5) "Equivalent drug product" means a product with the same generic name, active ingredients, strength, quantity, and dosage form as the drug product identified in a prescription;

(6)~~[(2)]~~ "Generic name" means the chemical or established name of a drug or pharmaceutical;~~[.]~~

(7) "Interchangeable biological product" means:

(a) A biological product that the United States Food and Drug Administration has licensed and determined meets the standards for interchangeability pursuant to 42 U.S.C. sec. 262(k)(4); or

(b) A biological product that the United States Food and Drug Administration has determined is therapeutically equivalent as set forth in the latest edition or supplement to the federal Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations;

~~[(3) "Practitioner" has the same meaning as in KRS 217.015.~~

~~(4) "Pharmacist" means any person licensed as such by the Kentucky Board of Pharmacy.~~

~~(5) "Equivalent drug product" means a product with the same generic name, active ingredients, strength, quantity and dosage form as the drug product identified in a prescription.~~

~~(6) "Board" means the Kentucky Board of Pharmacy.~~

~~(7)]~~***(8)*** "Nonequivalent drug product formulary" means a formulary of drugs, drug products, and dosage formulations for which there are no equivalent drugs, drug products, or dosage formulations and which have been determined to be noninterchangeable or to have actual or potential bioequivalency problems by the United States Food and Drug Administration and are contained in a drug bioequivalence problems list as published in the United States Food and Drug Administration publication entitled "Approved prescription drug products with therapeutic equivalence evaluations" with supplements;~~[.~~

~~(8) "Dosage formulation" shall include, but not be limited to, those specific dosage forms which, by the nature of their physical manufacture are deemed to be nonequivalent to other similar formulations such as controlled release tablets, aerosol nebulizer drug delivery systems and enteric coated oral dosage forms.]~~

(9) "Pharmacist" means has the same meaning as in KRS 315.010; and

(10) "Practitioner" has the same meaning as in KRS 217.015.

➔Section 2. KRS 217.822 is amended to read as follows:

(1) When a pharmacist receives a prescription for a brand name drug which is not listed by generic name in the nonequivalent drug product formulary prepared by the board, ***the pharmacist***~~[he]~~ shall select a lower priced therapeutically equivalent drug which ***the pharmacist***~~[he]~~ has in stock, unless otherwise instructed by the ***patient at the point of purchase***~~[purchaser]~~ or ***by the patient's***~~[his]~~ ***practitioner.***~~[physician, provided however that]~~ If ***a lower priced***~~[such]~~ selection is

made, the label on the container of the drug shall show the name of the drug dispensed.

(2) ***When a pharmacist receives a prescription for a brand name biological product which is not listed by name in the nonequivalent drug product formulary prepared by the board, the pharmacist shall dispense a lower priced interchangeable biological product, if there is one in stock, unless otherwise instructed by the patient at the point of purchase or by the patient's prescribing practitioner. If an interchangeable product is selected, the label on the container shall show the name of the biological product dispensed.***

(3) When an equivalent drug product ***or interchangeable biological product*** is dispensed in lieu of a brand name drug prescribed, the price of the equivalent drug ***or interchangeable biological*** product dispensed shall be lower in price to the purchaser than the drug product prescribed.

(4) ~~[(3)]~~ If, in the opinion of a practitioner, it is to the best interest of ***the practitioner's*** ~~[his]~~ patient that an equivalent drug ***or interchangeable biological product*** should not be dispensed, ***the practitioner*** ~~[he]~~ may indicate in the manner of his ***or her*** choice on the prescription "Do Not Substitute," except that the indication shall not be preprinted on a prescription.

(5) ~~[(4)]~~ The selection of any drug ***or interchangeable biological product*** by a pharmacist under the provisions of this section shall not constitute the practice of medicine.

(6) ~~[(5)]~~ A pharmacist who selects an equivalent drug product ***or interchangeable biological product*** pursuant to KRS 217.815 to 217.826 assumes no greater liability for selecting the dispensed drug product than would be incurred in dispensing a prescription for a drug product ***or biological product*** prescribed by its generic, ***nonbrand, or proper*** name.

(7) ~~[(6)]~~ When a pharmacist receives a generically written prescription for a multiple

source drug product, he ***or she*** shall dispense an equivalent drug product in accordance with the provisions of KRS 217.815 to 217.826.

(8) When a pharmacist receives a prescription for a biological product written by nonbrand or proper name, he or she shall dispense an interchangeable biological product in accordance with the provisions of KRS 217.814 to 217.826 provided that the interchangeable product has been deemed by the United States Food and Drug Administration to be interchangeable with that specific reference product as identified by the nonbrand or proper name.

(9) A pharmacist shall not substitute a biological product for a prescribed biological product unless the substituted product is an interchangeable biological product for the prescribed biological product.

(10) (a) Within five (5) business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall communicate to the prescribing practitioner the specific product provided to the patient, including the name of the product and the manufacturer.

(b) Communication shall be conveyed by making an entry that is electronically accessible to the prescribing practitioner through:

1. An interoperable electronic medical records system;

2. An electronic prescribing technology;

3. A pharmacy benefit management system; or

4. A pharmacy record.

(c) Communication entries into an electronic records system as described in this subsection are presumed to provide notice to the prescribing practitioner. Otherwise, the pharmacist shall communicate the biological product dispensed to the prescribing practitioner using facsimile, telephone, electronic transmission, or other prevailing means. Communication to the prescribing practitioner, or the prescribing practitioner's office personnel,

using facsimile, telephone, electronic transmission, or other prevailing means shall be presumed to provide notice to the prescribing practitioner.

(d) Communication shall not be required where:

1. There is no United States Food and Drug Administration-approved interchangeable biological product for the product prescribed;

2. A refill prescription is not changed from the product dispensed on the prior filling of the prescription; or

3. The prescribing practitioner indicates "Do Not Substitute" on the prescription.

(e) Communication received by the prescribing practitioner from the dispensing pharmacist or the pharmacist's designee shall be treated in accordance with the standards of acceptable and prevailing practice of the prescribing practitioner within the Commonwealth of Kentucky and the following as they relate to patient records:

1. The principles of ethics of the American Medical Association;

2. The code of ethics of the American Osteopathic Association;

3. The principles of ethics and code of professional conduct of the American Dental Association;

4. The code of ethics of the American Chiropractic Association;

5. The principles of veterinary medical ethics of the American Veterinary Medical Association;

6. The code of ethics of the American Optometric Association; or

7. The code of ethics for nurses of the American Nurses Association.

➔Section 3. KRS 217.216 is amended to read as follows:

(1) Every prescription order written by a practitioner authorized by statute to prescribe under this chapter and KRS Chapter 218A shall bear upon the prescription blank the name, telephone number, and business address of the prescribing practitioner.

(2) In order to provide a pharmacist sufficient information to meet the communication requirements of subsection (10)(c) of Section 2 of this Act, every prescription order written by a practitioner authorized by statute to prescribe a biological product under this chapter shall bear upon the prescription blank the name, telephone number, and business address of the prescribing practitioner in a clear and legible manner.

➔Section 4. KRS 217.895 is amended to read as follows:

(1) Routine inspections of pharmacies for compliance with KRS 217.815 to 217.826 shall be undertaken by the Kentucky Board of Pharmacy.

(2) Every pharmacy shall retain for a period of two (2) years from July 15, 1982, a pharmacy record of all prescribed drug ***and biological*** products dispensed. The pharmacy record shall be retained for the purpose of providing valid data for bona fide research and reporting to the General Assembly as to the effectiveness of KRS 217.815 to 217.826. The pharmacy record shall include:

(a) The brand name of the drug ***or biological product***, when applicable.

(b) The name of the manufacturer or the supplier of the drug ***or biological product***, if the drug ***or biological product*** has no brand name.

(c) The strength of the drug ***or biological product***, when significant.

(d) The quantity dispensed, when applicable.

(e) The serial number of the prescription.

(f) The date the prescription was originally dispensed and refilled.

(g) The name of prescribing ***practitioner***~~[physician]~~.

(h) The name of patient for whom the drug ***or biological product*** was prescribed.

(i) The price for which the drug ***or biological product*** was sold to the purchaser.

(j) A notation if the practitioner indicated "Do not substitute" or the purchaser refused the product selected.

President of Senate

Speaker-House of Representatives

Attest: Chief Clerk of Senate

Approved Governor

Date 9 APRIL 2016